CONSCIOUS SEDATION OF THE PEDIATRIC DENTAL PATIENT:

A COMPARISON OF MEPERIDINE VERSUS BUTORPHANOL

by
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INTRODUCTION

Dental treatment of pediatric patients can be a challenge for dentists, particularly for children below the age of 5 years. On occasion, the dentist needs to sedate a child patient in order to render dental treatment. Over the years, a variety of sedative agents and a variety of means of delivery have been used to sedate children for dental treatment with a range of success. The opiates have been a favored class of sedative medications to consciously sedate children and adults for dental treatment. While the opiates work well to sedate children, they also carry the unwanted side effect of respiratory depression.

Meperidine has been used widely in the medical and dental field for sedation of patients for years. Meperidine has been studied extensively for its efficacy in sedating pediatric dental patients. Butorphanol is also an opiate with sedating qualities and causes less respiratory depression than meperidine. Apparently, butorphanol has not been studied as a sedative medication for pediatric dental patients.

The hypothesis of the thesis is that intramuscular butorphanol will have equal or better quality as a sedative while displaying the same or fewer physiological effects on pediatric dental patients than intramuscular meperidine.

The null hypothesis is that intramuscular meperidine would provide a better level of sedation than an equipotent dosage of intramuscular butorphanol and produce fewer physiological effects on the patient.

REVIEW OF LITERATURE

Meperidine hydrochloride is a synthetic narcotic analgesic with actions similar to morphine. Meperidine hydrochloride's trade name is Demerol (Sanofi Winthrop).[1] The main therapeutic uses in the dental profession are for analgesia and sedation. Meperidine is an opiate agonist at both the mu and kappa opiate receptors with its effects at the mu receptor being responsible for sedation, analgesia, respiratory depression, and physical dependence.[2] Meperidine is contraindicated in individuals receiving monoamine oxidase inhibitors, patients with a history of head injury or increased intracranial pressure, patients with compromised respiratory function or low SaO_2, patients with severe hypotension, and in patients who are pregnant or breast-feeding.[1] Its oral effectiveness is around one-fourth of its parenteral effectiveness.[2] The onset of action is more rapid than morphine, and the duration is shorter. Meperidine is approximately eight to 10 times less potent than morphine. In addition, it produces less smooth muscle spasm, less constipation, and less depression of the cough reflex than equianalgesic doses of morphine. When given parenterally at equianalgesic doses, the degree of sedation and respiratory depression are the same for both morphine and meperidine.[3] The side effects of meperidine are well-documented and may include respiratory depression and arrest, nausea, vomiting, constipation, pruritus, and urinary retention.[1] Meperidine is known to be the opioid most commonly abused by health professionals.[2] According to the US Controlled Substances Act of 1970, meperidine is considered a schedule II substance, which indicates a high abuse potential with severe psychic or physical dependence

liability.[3]

Butorphanol tartrate is a synthetic narcotic analgesic with agonist-antagonist actions. Butorphanol's trade name is Stadol (Bristol-Myers Squibb Co.), and it is primarily used as a pain reliever and can be used secondarily as a sedation drug (pre-anesthetic).[1] Butorphanol is water-soluble. Its metabolism occurs mainly in the liver and is excreted primarily in the urine. Its half-life is 2.5 hours.[1] Butorphanol and its major metabolites have agonist effects at the kappa-opioid receptors, agonist/antagonist effects at the mu-opioid receptors, and agonist effects at the sigma receptor. Butorphanol's agonist effects at the kappa receptor are most likely responsible for its sedative qualities, while its antagonist effects at the mu receptor and its agonist effects at the sigma receptor are responsible for its limited respiratory depression.[4] The sedative effects of Butorphanol in animals have been described as apathetic sedation.[5] While the sedative effects can be very striking, even in very large doses of 0.3-1.0 mg/kg, it does not produce a state of anesthesia in humans.[5] The potency is approximately five times that of morphine and around 30 to 40 times that of meperidine. One mg of butorphanol is equal to approximately 40 mg of meperidine.[2] Butorphanol's antagonist activity at the mu receptor is one-fortieth of the activity of naloxone at that receptor.[4] Peak oral absorption is 1.5 hours, but only 17 percent of the drug is biologically available after first-pass liver metabolism.[6] In order to reach clinical efficacy the oral dose must be 4 to 5 times higher than the intramuscular (I.M.) or intravenous (I.V.) dosage.[6] The onset of analgesia is 30 minutes or less following intramuscular administration with a duration of action of 3 to 4 hours.[1] Adverse reactions include somnolence (43 percent), dizziness (19 percent), and nausea or vomiting (13 percent).[1] Central nervous system excitation rarely occurs (1 to 2

percent) and has been described as euphoria, dysphoria, hallucination, disorientation, confusion, agitation, and unusual dreams.[6] Butorphanol produces less nausea and vomiting than meperidine or morphine.[7] The "frozen chest" syndrome, known to occur with fentanyl, has not been observed with butorphanol.[6] Physiologic cardiac effects include increased pulmonary wedge pressure, increased pulmonary artery pressure, increased left ventricular end-diastolic pressure, increased systemic arterial pressure, increased pulmonary vascular resistance, increased cardiac index, and increased cardiac work.[4] Butorphanol appears to be chemically and physically compatible in the same solution with atropine, hydroxyzine, and promethazine.[6] Overdose has not been a clinical problem with butorphanol, because it has an outstanding history for safety and a low abuse record.[4, 8] Butorphanol is a controlled substance as a schedule IV medication.[3]

A majority of clinical studies on butorphanol have been on adults. In a 1976 study by Tavakoli et al. in which I.M. butorphanol was compared with equianalgesic doses of I.M. morphine, butorphanol was found to be safe and effective with minimal side effects.[9] In a 1977 study by Lippmann et al. again comparing I.M. butorphanol with I.M. morphine, it was found that butorphanol was rated 94 percent effective or partially effective, and drowsiness was the major side effect in 88 percent of the patients.[10] When I.M. meperidine and I.M. butorphanol were compared in a 1976 study by Gilbert et al., it was found that a 0.028 mg/kg of butorphanol provided relief from moderate to severe postsurgical pain in a manner that was statistically indistinguishable from that of 1.14 mg/kg of meperidine.[11] In treatment of postanesthesia shaking, I.V. butorphanol was found to be more effective than I.V. meperidine in a 1992 study by Vogelsang and Hayes.[7] In a 1986 study by Finucane et al., it was found that I.M. butorphanol was

comparable to I.M. dezocine, another agonist-antagonist opiate, for postoperative pain.[12] Intravenous Butorphanol was found to be similar in sedative properties when compared with I.V. midazolam. In a 1991 study by Dershwitz et al., using I.V. dosages of 0.007 mg/kg, 0.022 mg/kg, and 0.071 mg/kg of butorphanol, it was found that significant sedation could occur at doses less than those usually needed for analgesia without patient amnesia or impairment of psychomotor function.[13] The clinical studies show a wealth of information of butorphanol use in human adults with a favorable side-effect profile.

There are very few studies that evaluate butorphanol in pediatric patients. In a 1988 study by Steg of I.M. butorphanol for treatment of postoperative orthopedic pain in adolescents using a mean dosage of 0.044 mg/kg, 89 percent of the patients had good to excellent pain relief.[14] A 1995 study by Splinter et al. that compared I.V. butorphanol at 0.03 mg/kg with I.V. morphine at 0.15 mg/kg in children (mean age ~5 years old) found that butorphanol reduced vomiting by 50 percent without an increase in adverse events, when given during the operative period for postoperative pain.[15] A 1994 study by Lawhorn and Brown, comparing a combination of butorphanol 0.04 mg/kg and morphine 0.08 mg/kg with morphine 0.08 mg/kg only for epidural anesthesia in children, found a decrease in the incidence of side effects without a decrease in analgesia.[16] In another study by the same primary author in 1994 comparing children (mean age ~7.6 years old) undergoing dorsal rhizotomy, who were given epidural butorphanol and morphine or morphine alone in the above dosages, it was found that the butorphanol/morphine group had a significantly reduced incidence of nausea, vomiting, and pruritus.[17] In a 1981 study it was found that intramuscular butorphanol in doses ranging from 0.01-0.02 mg/kg to be safe and effective (100-percent pain relief for a minimum of one hour) in treating

postoperative pain in children (mean age ~7.9 years old).[6] However, there has been extensive pediatric experience with butorphanol in the Riley Children's Hospital recovery room, where it has been used intravenously for over six years for postoperative analgesia. The drug is also used on a daily basis in the Riley cardiac catheterization laboratory as a sedative analgesic. In these settings, butorphanol has been found to be safe and effective when administered to pediatric patients.

Butorphanol and meperidine are both capable of causing respiratory depression, but butorphanol exhibits a ceiling effect. Increasing the dose will lower minute ventilation to a point, but further increases result in no further decrease in minute ventilation; the increases will only lengthen the duration of the respiratory depression.[4] Butorphanol has an excellent safety record and a large quantity of clinical experience.[5] Naloxone (Narcan) is a potent antagonist capable of reversing the effects of both meperidine and butorphanol.[1]

Both drugs are capable of causing nausea and vomiting, because they have a direct effect on the chemoreceptor zone, but this may also be related to the dosage administered.[18] The maximum I.M. recommended dose of Demerol according to the 1996 Physician's Drug Reference (PDR) is 2.2 mg/kg, up to a total dose of 100 mg.[1] McKee et al., in studying dose responsiveness to meperidine, found that it was effective as a sedative at 0.5 mg/lb and at 1.0 mg/lb, but the incidence of nausea and vomiting was higher at the 1.0 mg/lb dose.[19] Butorphanol's propensity for causing nausea and vomiting appears to be also dose-related.[11] In the previously mentioned adult study by Gilbert et al., utilizing butorphanol intramuscularly, it was found that nausea occurred predominantly at the highest dose, approximately 0.057 mg/kg.[11]

Meperidine is usually reserved for the dental patient with extreme fear-related or stubborn-defiant behavior. Various forms and combinations of meperidine use have been studied with varying success rates. In the previously mentioned study by McKee et al., using varying doses of intramuscular meperidine for pediatric dental patients, it was found that 80 percent of the 0.5 mg/lb patients and 73 percent of the 1.0 mg/lb patients were rated as having good to excellent sedation on the global rating scale.[19] In a 1993 study of emergency room pediatric patients (~ average of 4 years old), the patients received 2.0 mg/kg of meperidine and 1.0 mg/kg of promethazine with or without 1.0 mg/kg of chloropromazine.[20] It was found that 74.4 percent of the group with chloropromazine was rated moderately to well-sedated, while 65 percent of the group without chloropromazine was rated moderately to well-sedated. In a 1992 study by Roberts et al., it was found that 2.2 mg/kg of meperidine and 1.1 mg/kg of promethazine given orally to moderately uncooperative pediatric dental patients was successful 58 percent of the time in modifying behavior.[21] Good sedation was found in 45 percent of pediatric dental patients that received 2.0 mg/kg of meperidine and 0.5 mg/kg of promethazine orally in a 1993 study by Alfonzo-Echeverri et al.[22] A range of efficacy for sedation for dental treatment with meperidine can be determined from the previously mentioned studies.

Nitrous oxide has been used in dentistry since 1844.[23] When used in conjunction with oxygen, it can effectively and safely provide mild sedation and reduce dental anxiety. The absorption of nitrous oxide is through the alveoli and its clinical effects are rapid. It is not metabolized and is excreted through the lungs at a rate similar to its absorption. One-hundred-percent oxygen is usually administered at the completion of

dental procedures to prevent nausea and diffusion hypoxia associated with the nitrous oxide.[24] The incidence of nausea and vomiting related to nitrous oxide is low and does not appear to be related to the concentration (below 50 percent), duration, patient age, or patient health status.[25] The main reported disadvantage of nitrous oxide is its effect on the reproductive system in individuals chronically exposed to high levels of the gas. This finding was discovered through studies of those dentists and dental assistants who were exposed to nitrous oxide. They showed a higher spontaneous abortion rate and a lower fertility rate, most likely due to work environments without scavenging systems.[26] The added advantage of using oxygen with the nitrous oxide is the ability to keep a sedated patient well-oxygenated (fail-safe mechanism does not allow oxygen below 30 percent). Hasty et al. supplemented their sedated pediatric patients with oxygen and noted a low incidence of desaturation (SaO_2<96%) during the course of their dental treatment.[27] Nitrous oxide is used to enhance the effect of the sedative or analgesic medications.

Management of the uncooperative child with extensive dental needs may require the use of pharmacological agents in those situations where non-pharmacological behavior management has been unsuccessful. Behavior management can be especially challenging with younger children. In two Swedish studies of three-year-old children undergoing first dental visits, negative behavior rates were found to be 32 percent and 11 percent of the children seen.[28] In a 1991 study of Hispanic children by Steelman, it was found that 30 percent of three- and four-year-olds undergoing dental treatment were unmanageable using standard non-pharmacologic behavior management techniques.[29] Dentists may increase the use of in-office conscious sedation as opposed to the use of general anesthesia in the hospital operating room because of the cost increases that

general anesthesia would pose to either the patient or the insurance company. In-office sedation and general anesthesia have a reportedly favorable mortality and morbidity rate of 1:137,000-860,000, compared with the mortality and morbidity of general anesthesia in the hospital of 1:10,000-19,000.[30, 31]

Butorphanol has been evaluated in adult patient populations for sedation for dental treatment in several studies. In a 1986 study by Day et al., comparing butorphanol/diazepam and fentanyl/diazepam in I.V. form for outpatient third molar extraction, it was found that the butorphanol/diazepam combination was clinically satisfactory and gave a greater degree of conscious sedation in comparison with the fentanyl/diazepam combination.[32] In a study by Zallen et al. in 1987, a comparison of butorphanol/diazepam versus meperidine/diazepam for multiple extractions with I.V. sedation, it was found that the butorphanol/diazepam combination was superior to the meperidine/diazepam combination in regard to the diazepam dose required to achieve the desired level of sedation, the total diazepam dose, the level of clinical sedation, and in patient evaluation parameters.[33] In another 1987 study by Abo El Fadl et al., it was found that I.V. butorphanol given prior to local anesthesia caused patients receiving periodontal surgery to be more stable in their vital signs, show fewer clinical changes, and require less time with their surgery when compared with a placebo (sterile saline).[34] In a 1987 study by Mekkey,[35] it was shown that, when compared with I.V. midazolam in the dosage of 0.06 mg/kg given prior to local anesthesia in patients for third molar extraction, intravenous butorphanol in the dosage of 0.015 mg/kg had good anxiolytic properties while maintaining patient consciousness. A 1987 study by Jann et. al. found that butorphanol was clinically effective 74.8 percent of the time with the dosage of

approximately 0.02 mg/kg and that sedation occurred in 28.2 percent of the trials,[36] when it was given intramuscularly to severely and profoundly retarded patients (previously refractory to treatment with chloral hydrate) as a premedication for dental treatment. Upward dosage titration to an average of 0.04 mg/kg increased efficacy to 85.0 percent.

Pediatric dentists have used combinations of oral and I.M. medications for many years with varying degrees of success. Two frequently used agents are chloral hydrate (Noctec) and meperidine hydrochloride (Demerol). Both of these agents, when used properly, can achieve a minimal level of depressed consciousness that does not alter the patient's ability to maintain a patent airway independently and respond appropriately to verbal commands.

Some pediatric dentists may be reluctant to use Demerol in their offices due to its potential to cause respiratory depression.[1] Chloral hydrate's use has been increasing due to its tendency to cause less respiratory depression and its high margin of safety. Overall, chloral hydrate has an outstanding safety record, but many case reports of mortality and morbidity have been reported. These reports include supraventricular and ventricular arrhythmias, severe esophageal and gastric irritation with necrosis, life-threatening hypotension, respiratory arrest, and even induced laryngospasm and cardiac arrest associated with rapid introduction into the oral pharynx with a syringe.[23] Chloral hydrate's sedative effect cannot be reversed as is possible with a narcotic agent, and there is some growing concern in the scientific and medical communities that a metabolite of chloral hydrate may be carcinogenic.[37,38] Chloral hydrate has been shown in several studies with rodents to induce hepatocarcinoma when given in chronic high doses. On the other hand, chloral hydrate has shown no clinically significant increase of carcinoma

in humans.[38] If the availability of chloral hydrate decreases, there will be a renewed interest in other safe and effective sedative agents.

Physiologic monitoring is an important aspect of sedation study methodology in order to document drug side effects and patient safety. Pulse oximetry is considered by those involved in sedation as the standard for patient monitoring.[39] It is an indirect measure of oxygen saturation of the blood and heart rate. Usually oxygen saturation is stable during sedations with only an occasional desaturation. Blood pressure is another measure that can be obtained with either a manual blood pressure cuff or with an automated blood pressure cuff. In conscious sedation dosage ranges, most sedative drugs will not cause a significant clinical change in blood pressure. In a 1995 study by Croswell et al., electronic monitoring showed 10 episodes of confirmed respiratory compromise, while traditional monitoring (visual assessment, precordial stethoscope, and palpation) only identified three of the same episodes.[40] The American Academy of Pediatric Dentistry 1997-98 guidelines for conscious sedation recommend that the level of patient consciousness, the patient's airway patency, pulse oximetry, heart, and respiration rates be monitored throughout the operative period.[41]

A child's behavior can vary from one end of the behavior spectrum to the other. During a dental appointment, both ends of the behavior spectrum can be displayed, which makes rating a child's behavior a difficult undertaking. A child's behavior can be assessed through several different means and times. A child can be evaluated by parent interview before the appointment using the Eyeberg Child Behavior Inventory. However, in a 1994 study by Dunegan et al., the inventory was shown to be a poor predictor of disruptive or cooperative behavior within the dental setting.[42] In a 1993 study by Lochary et. al., it was

found that the Toddler Temperament Scale predicted struggling behavior during sedation from children with the approach/withdrawal tendency.[43] A similar finding was reproduced in a 1994 study by Radis et al., in which approach/withdrawal and adaptability could predict quiet behavior in three-year-old patients undergoing initial dental exams.[44] In a 1994 study by Sanders et al., it was found that a well-rested child preoperatively is associated with a more successful sedation with chloral hydrate and hydroxyzine.[45] While these instruments have their place, intraoperative evaluation of behavior has been the gold standard of rating the efficacy of sedation drugs in the dental setting.

Any study of anxious behavior of the patient in the dental setting should include subjective self-report measures, physiological measures, and behavioral measures.[46] While the information gained from adults' self-reports can be valuable, in young children (<5 years old) it is hard to obtain accurate information due to the lack of verbal skills and comprehension. Physiologic parameters are of utmost importance to measure the side effects of sedative medications and the physical status of the patient, but such parameters are of little value in measuring patient anxiety or general patient behavior. Any objective behavioral measure should have reliability and validity, low bias, be versatile for both clinical and laboratory application, and give numbers on an identifiable number scale.[46] One way to minimize bias is called blinding or masking. In blinding the patient, the dental operator and the behavior raters are unaware of which treatment group the patient is from.[47] A double-blind study is a study in which all three individuals listed above are blinded. In order to give a sedation study, reliability raters are calibrated and scales standardized against those scales whose reliability is known. These methods are difficult

to execute in clinical studies in order to render even simple conclusions.

Behavior rating scales can be separated into two types, global and restricted scales.[47] A global scale utilizes a single measure for the overall behavior of a subject for the entire appointment. Examples of global rating scales would be the Frankl scale, the Visual Analogue Scale (VAS), and the Global Rating Scale. In a 1995 study by Hosey and Blinkhorn comparing the Frankl scale, the VAS, the Global Rating Scale, and the Houpt Scale, the Frankl scale had poor agreement between the raters and should be considered an unreliable measure of patient behavior.[48] In another study in 1991 by Tafaro et al., the Frankl Scale had less agreement between raters than the North Carolina Behavior Rating System (NCBRS).[49] The VAS showed low correlation between raters in a 1988 study by Parkin.[50] While global scales are simple to use and more practical in a clinical setting, they have the disadvantage of being affected subjectively by an extreme in behavior for a relatively short period of time by the patient. A restricted scale is a measure of specific behaviors that are defined at either specific milestones, time intervals, or continuously. Examples of restricted scales include the Houpt Scale, the NCBRS, and the Ohio State University Behavior Rating Scale (OSUBRS). These rating scales have the advantage of giving a more complete reflection of the child's behavior throughout the sedation and are more sensitive to differences in treatment groups. The disadvantages of these scales are that they are more time-consuming for the rater.[47] Due to the need for extensive recall on the part of the rater, videotaping of the sedation appointment is most essential for accuracy.

While different rating scales can be used to assess a child's behavior, different rating time intervals also can be used. The behavior can be rated as a one-time global

rating at the end of the sedation, at certain milestones during the course of the sedation (i.e. injection, rubber dam placement), at a certain interval of time (i.e. every 15 minutes), or continuous rating of the behavior over the course of the entire sedation. A one-time global rating of a child's behavior is very subjective, because the child's behavior is rated over a time interval that is condensed to a one-time rating. It can be affected by an extreme in unsatisfactory behavior that occurred only for a few moments. When the behavior is rated at certain milestones during the treatment (local anesthetic injection, rubber dam placement), the assessment can also be skewed, because the patient might receive stronger stimuli from the particular procedures selected, which can also be close in time. Rating a child's behavior in certain time intervals is a consistent means of evaluation, but it does not allow for dips in behavior between the rating points. Continuous rating of a child's behavior over the course of the entire sedation is the most consistent and accurate means to rate a child's behavior. The child's behavior can be given a rating based per unit of time, which gives a clear overall picture of the child's behavior over the course of the sedation.[47] In a 1981 study by Chambers et al., four behaviors in non-sedated children were consistent with disruptive behavior.[51] The four behaviors were titled as high-hands, leg movements, crying protest, and oral-physical resistance. This four-category rating scale is known as the NCBRS or North Carolina Behavior Rating Scale. It gives raters of behavior an objective means of rating behavior by looking for certain behaviors that are considered disruptive. This helps standardize the rating of what is considered bad versus good behavior instead of rating behavior based on the individual viewer's opinion.

Hasty et al. in a 1991 study combined the NCBRS with a computer program

(Automated Coding System, version 1.0, JAGTECH, Rockville, MD) to rate videotaped behavior of children under sedation with either chloral hydrate, hydroxyzine pamoate, and meperidine or chloral hydrate and hydroxyzine pamoate.[27] Behavior was rated continuously with the computer program coding each change in behavior on a four-point behavior category scale and measuring the time during which the behavior was displayed. At the end of the sedation, the data were converted into a percentage of total time of the sedation for each of the four behavior categories. This allowed for complex statistical analysis of the data for a relatively small sample size of 10 children. The findings indicated a statistically significant improvement with the addition of meperidine 1.5 mg/kg. This computer program has been used to rate behavior in at least five studies using the OSUBRS.[43,44,52]

The use of intramuscular butorphanol (Stadol) may prove to be a viable and perhaps superior alternative to traditional regimens for sedation of children during dental restorative procedures. Butorphanol results in more sedation when compared with meperidine and may have fewer side effects than meperidine. In addition, butorphanol does not have the abuse and addiction potential associated with Demerol.

METHODS AND MATERIALS

Patients presented to James Whitcomb Riley Hospital for Children Dental Clinic were eligible for this study. There was a need for dental restorations and extractions. Forty sedations were carried out on eligible children. Only healthy children (American Society of Anesthesiology Class 1) between the ages of 13 months and 62 months were eligible for participation in this study. A history and physical were completed within three months preceding the dental treatment. There was no evidence of enlarged tonsils or a history of upper respiratory infection within one month of the planned dental sedation. The patient behavior was negative or definitely negative based on the Frankl scale (Appendix 1) at the time of the initial dental visit, and the child had failed to respond to non-pharmacologic behavior modification. An informed written and verbal consent was obtained as approved by the Institutional Review Board.

The parents were given a standard Riley dental sedation protocol (Appendix 2). The preoperative instructions were reviewed with the patient's parent at an appointment prior to the dental procedure.

The children selected were randomly assigned to two groups. Group A received Demerol (Sanofi Winthrop) 2.0 mg/kg intramuscularly and group B received Stadol (Bristol-Myers Squibb Co.) 0.03 mg/kg intramuscularly. The injections were given in the upper outer quadrant of the right or left lateral thigh into the Vastus Lateralis muscle. In this double-blind study, the dentist performing the dental treatment, the dentists viewing the video (raters), the patients, and the patients' parents were unaware of the treatment

group assignment. All patients were monitored using the guidelines established by the Academy of Pediatric Dentistry for the elective use of conscious sedation, deep sedation, and general anesthesia in pediatric patients.[41] A positive pressure oxygen delivery system capable of administering 100-percent oxygen at a 5 l/min flow was available. A backup emergency service was currently set up with an established protocol for immediate deployment with the Riley Hospital Department of Anesthesia. An emergency cart containing the necessary drugs and equipment to resuscitate a non-breathing and unconscious patient was in the operatory.

After 30 minutes, the clinical onset of sedation, the patient was brought back to the operatory and placed in a papoose board (Olympic Medical Group, Seattle, WA) with the appropriate physiologic monitors: precordial stethoscope and MDE Escort monitor (non-invasive blood pressure cuff, pulse rate, ECG, and oxygen saturation) were placed. Digital palpation was used to monitor the patient's respiratory rate. The patient received supplemental nitrous oxide and oxygen at a concentration not to exceed 50-percent nitrous oxide. The dental operator adjusted the flow rate and concentration based on the patient's behavior. Following completion of the dental procedure, the patient received 100-percent oxygen for a period of five minutes. Two-percent lidocaine with 1:100,000 epinephrine was used for local anesthesia not to exceed the cumulative dosage of 4.4 mg/kg. At any time during the procedure, if the sedation was inadequate, the dental treatment was discontinued. Dental treatment consisted of amalgam restorations, resin restorations, stainless steel crowns, and extractions. Upon completion of the dental sedation, the patient was discharged when cardiovascular and airway stability were assured, and when the patient was alert and ambulatory. During the recovery period the

patient's oxygen saturation was monitored with the pulse oximeter and by visual observation. The patient's chart contained documentation that the heart rate, blood pressure, color, oxygen saturation, and responsiveness were checked before the medication was given (baseline), and during the sedation itself (every 5 minutes), and at the time of discharge. The chart also contained the patient's race, gender, age in months, weight in kilograms, and all the types and numbers of dental treatment accomplished.

The MDE escort monitor (Medical Data Electronics, Alerta, CA) utilized in this study provided the monitoring of blood pressure, oxygen saturation, ECG, and heart rate on a continuous basis. Group A and B were evaluated for any statistically significant changes in these physiologic parameters.

All sedation appointments were videotaped using a VHS video camera. Taping commenced from the time the patient was brought into the operatory to begin the operative treatment until the patient was dismissed into the recovery room after operative treatment. The view of the videotapes included the patient's entire body filmed consistently from the same position in the treatment room. The videotapes of the sedation were reviewed by three observers independently to achieve an objective behavioral assessment of the dental sedation.

The ACS or Automated Coding System (Version 1.0, JAGTECH, Rockville, MD 1987) was used by the observers as an assessment tool of the child's behavior on a chronologically continuous basis. The observers that watched the sedation pressed one of four buttons (Appendix 3) depending on the patient's behavior. The modified NCBRS, as described by Hasty et al. in 1991,[27] was used to look at the four undesirable behaviors of foot movement, torso movement, head movement, and crying. This behavior rating

scale begins with the most desirable behavior rating of Quiet, proceeds to Annoyed, then to Upset, and ends with the most undesirable behavior rating of Zoo. At the end of the sedation the coding session was stored and processed using the same program. The results of the program data analysis revealed total time of sedation, total time spent in each behavior category, the minimum and maximum time spent in each behavior category, and the number of occurrences of each behavior category type.

Another assessment tool used to evaluate the dental sedation was the categorical scale that evaluates crying, apprehension, cooperation, and sleep, which is useful when comparing different drugs where qualitative and quantitative drug effects are being evaluated. Using this categorical scale (Appendix 4) the patient's behavior was evaluated five times during the procedure: immediately prior to beginning of operative treatment, during local anesthetic administration, during rubber dam placement, during cavity placement, and during carving of the restoration.

A second scale, the dichotomous scale (Appendix 5) developed by Moore et al.,[53] was also used for this study. This scale was based on the presence or absence of a behavior and eliminates the quantification, which can be interpreted differently from one observer to another. It has high inter-rater reliability and is useful when assessing the safety of pharmacologic agents.

Lastly, the dentist performing the restorative treatment and administering the medication rated the sedation using the dichotomous scale, sedation success and a global rating scale (Appendix 6). This rating can be compared with the independent raters evaluation to note the differences between the perceptions of the operator and outside independent raters. Operators evaluated the airway status of each patient by tilting the

patient's chin towards the patient's chest and checking to see if the patient maintained his or her airway independently once the head was released.

STATISTICAL ANALYSIS

One-way ANOVA models were used to compare group A and group B for differences in baseline means for the physiologic parameters (systolic and diastolic blood pressure, oxygen saturation, heart rate, and respiration rate) using repeated measures analysis of variance. Analysis of covariance (ANCOVA) models were used to compare group A and group B for differences in means during treatment for the physiological parameters by using the baseline parameters as covariates. One-way ANOVA models were also used to compare group A and group B for differences in means during treatment for the physiological parameters. Fisher's Exact tests were used to compare the patients in group A and group B for differences in race and gender and in the percentages of patients receiving stainless steel crowns, resin restorations, amalgam restorations, or extractions. One-way analysis of variance (ANOVA) models were used to compare the patients in group A and group B for differences in mean age (in months) and weight (in kilograms).

ACS ratings for groups A and B were compared for differences in total sedation time, total number of code changes, time to behavior change, and percentage of time spent in each behavior category using analysis of variance (ANOVA) models with subject and viewer as random effects and group as a fixed effect. The analyses for the percentage of time spent in each behavior category were made after using a variance-stabilizing transformation (arcsine-square root percentage). The three independent viewers' ratings

of Group A and group B were compared for differences in sedation in operatory, sedation in operatory with nitrous oxide, and reaction to injection by using generalized estimating equation (GEE) methods applied to logistic regression. GEE methods were necessary to correlate the ratings by multiple viewers on the same subject. Group A and group B were also compared for differences in global rating scale, crying, cooperation, apprehension, and sleep by using GEE methods applied to cumulative logistic regression.

Fisher's Exact tests were used to compare the operator's ratings for group A and group B for differences in pre- and post-treatment Frankl, sedation in quiet room, sedation in operatory, sedation in operatory with nitrous oxide, and reaction to injection. Cochran-Mantel-Haenszel tests for ordinal data were used to compare group A and group B for differences in sedation success and global ratings of the operator.

RESULTS

The meperidine and butorphanol groups did not have statistically significant different mean age ($p = 0.6947$) or weight ($p = 0.3676$) (Table I).

The meperidine and butorphanol groups did not show a statistically significant different percentage between race ($p = 1.000$) or gender ($p = 0.748$) in the patient groups (Table II). Forty percent of the meperidine and butorphanol groups' patients were caucasian and 60 percent were non-white respectively. The meperidine and butorphanol groups did not have statistically significant different percentage of stainless steel crowns ($p = 1.000$), resin restorations ($p = 1.000$), or amalgam restorations ($p = 0.605$) (Table II). There was slight evidence of more patients with extractions ($p = 0.054$) in the butorphanol group than in the meperidine group (Table II).

The meperidine and butorphanol groups did not have significantly different mean pulse ($p = 0.1616$), systolic blood pressure ($p = 0.2691$), diastolic blood pressure ($p = 0.8831$), respiration rate ($p = 0.7471$), or oxygen saturation ($p = 0.5473$) at baseline (Table III). One patient was missing baseline pulse and one patient was missing baseline diastolic blood pressure. Sixteen of the 40 patients had an oxygen saturation measurement at baseline.

Four patients were missing systolic blood pressure data during treatment. Fifteen patients were missing diastolic blood pressure data during treatment. Twelve patients were missing respiration rate data during treatment. All patients in both groups had an electrocardiogram that stayed at normal sinus rhythm from baseline and throughout

treatment. For the physiologic parameters recorded, the meperidine and butorphanol groups did not have significantly different mean pulse ($p = 0.2917$), systolic blood pressure ($p = 0.4776$), diastolic blood pressure ($p = 0.2217$), or respiration rate ($p = 0.5745$) during treatment (Table IV). The meperidine group had a higher mean oxygen saturation during treatment than the butorphanol group.

The meperidine and butorphanol groups were not statistically significantly different when total sedation time was compared ($p = 0.2058$) (Table V). The mean total sedation time of the meperidine group was 3535.38 sec while the butorphanol group's mean time was 3111.13 sec.

The two groups were not statistically significantly different when the total number of code changes were compared ($p = 0.4356$) (Table VI) and were not statistically significantly different when time to behavior change was analyzed ($p = 0.2111$) (Table VII).

The groups did not spend a statistically significant different percentage of time in the Upset ($p = 0.45$) or Zoo ($p = 0.60$) categories respectively. The butorphanol group spent significantly more time in the annoyed category ($p = 0.0238$) and showed a trend toward less time spent in the quiet category ($p = 0.0886$) (Table VIII).

The groups' sedation in operatory ratings were not statistically significantly different ($p = 1.0000$) (Table IX).

The groups' sedation in operatory with nitrous oxide ratings were not statistically significantly different ($p = 0.7076$) (Table X).

The groups' reaction to injection ratings were not significantly different ($p = 0.0630$) (Table XI).

The groups' global scale ratings were not statistically significantly different ($p = 0.2909$) (Table XII).

The groups' crying ratings were not statistically significantly different ($p = 0.0685$) (Table XIII).

The groups' cooperation ratings were not statistically significantly different ($p = 0.2100$) (Table XIV).

The groups' apprehension ratings were not statistically significantly different ($p = 0.2139$) (Table XV).

The groups' sleep ratings were not statistically significantly different ($p = 0.2533$) (Table XVI).

The meperidine and butorphanol groups did not have statistically significantly different pre- ($p = 0.741$) and post-treatment Frankl ($p = 0.751$), sedation in quiet room ($p = 1.000$), sedation in operatory ($p = 0.191$), sedation in operatory with nitrous oxide ($p=0.320$), and reaction to injection ratings from the operator ($p = 0.517$) (Table XVII).

The meperidine and butorphanol groups did not have statistically significant different sedation success ratings of the operator ($p = 0.146$). There was some evidence that the meperidine group had a statistically significant better global rating than the butorphanol group ($p = 0.072$) (Table XVIII).

Four of the subjects had 2 sedations, so that they were given one medication each time. All of the patients in both groups had their airway rating as clear in both the operatory and in operatory with nitrous oxide. No oxygen desaturations (<96-percent oxygen saturation) were noted with either group. No immediate perioperative complications were noted with either group.

FIGURES AND TABLES

TABLE I

Age (months) and weight (kilograms) of the meperidine and butorphanol groups

	Age (Months)		Weight (Kilograms)	
Group	Mean	Standard Deviation	Mean	Standard Deviation
A (Meperidine)	34.60	10.96	15.20	2.53
B (Butorphanol)	33.40	8.01	14.49	2.43
p-value	0.6947		0.3676	

TABLE II

Fisher's Exact test results for race and gender and the percentages of patients receiving stainless steel crowns, resin restorations, amalgam restorations, and extractions

		A (Meperidine)		B (Butorphanol)		
Category	Response	#	percent	#	percent	p-value
Race	White	8	40	8	40	1.000
	Non-white	12	60	12	60	
Gender	Female	9	45	7	35	0.748
	Male	11	55	13	65	
Stainless Steel Crowns	Yes	10	50	9	45	1.000
	No	10	50	11	55	
Resin Restorations	Yes	16	80	16	80	1.000
	No	4	20	4	20	

(continued)

(continued)

TABLE II

Fisher's Exact test results for race and gender and the percentages of patients receiving stainless steel crowns, resin restorations, amalgam restorations, and extractions

Amalgam	Yes	3	15	1	5	0.605
	No	17	85	19	95	
Extractions	Yes	5	25	12	60	0.054
	No	15	75	8	40	

TABLE III

Baseline means for the physiological parameters
and one-way ANOVA analysis results

	Meperidine		Butorphanol		p-value
Physiologic Sign	Mean	Standard Deviation	Mean	Standard Deviation	
Pulse	105.53	14.80	112.60	16.06	0.1616
Systolic B.P.	91.85	16.77	97.35	14.13	0.2691
Diastolic B.P.	57.26	10.22	57.75	10.31	0.8831
Respiration Rate	24.25	4.77	24.65	2.76	0.7471
Oxygen Saturation	99.67	0.52	99.50	0.53	0.5473

TABLE IV

ANCOVA analysis of comparing means during treatment for physiological parameters using the baseline parameters as covariates*

	Meperidine		Butorphanol		p-value	
Vital Signs	Mean	S. D.	Mean	S.D.	ANOVA	ANCOVA
Pulse	125.67	28.40	132.95	21.76	0.3686	0.2917
Systolic B.P.	103.52	16.53	100.34	10.14	0.4917	0.4776
Diastolic B.P.	58.82	11.83	64.00	8.34	0.2152	0.2217
Resp. Rate	25.14	2.64	25.86	3.34	0.5280	0.5745
Oxygen Sat.	99.63	0.48	99.20	0.56	0.0116	0.0806

* One-way ANOVA analysis to compare the groups for differences in means during treatment for the physiological parameters because of missing baseline data.

TABLE V

Total sedation time

Viewer 1

Group	#	Mean	S.D.	S.E.	Minimum	Maximum
B	20	3124.60	967.63	216.37	1067.00	5756.00
A	20	3543.95	1130.86	252.87	407.00	5442.00

Viewer 2

Group	#	Mean	S.D.	S.E.	Minimum	Maximum
B	20	3137.95	967.32	216.30	1126.00	5800.00
A	20	3550.00	1139.67	254.84	388.00	5475.00

Viewer 3

Group	#	Mean	S.D.	S.E.	Minimum	Maximum
B	20	3070.85	980.68	219.29	1314.00	5758.00
A	20	3512.20	1147.12	256.50	403.00	5438.00

(continued)

(continued)

TABLE V

Total sedation time

Group	#	Average Mean	S.D.	S.E.	Minimum	Maximum
B	20	3111.13	957.75	214.16	1169.00	5771.33
A	20	3535.38	1137.63	254.38	399.33	5445.00

TABLE VI

Total number of code changes

ViewerGroup	#	Mean	S.D.	S.E.	Minimum	Maximum
1	B	20	29.40	20.16	4.51	2.00	63.00
	A	20	23.70	19.93	4.46	2.00	81.00
2	B	20	28.15	20.02	4.48	4.00	75.00
	A	20	22.25	19.95	4.46	2.00	80.00
3	B	20	77.05	43.32	9.69	13.00	157.00
	A	20	68.55	55.07	12.32	5.00	193.00
Average	B	20	44.87	24.36	5.45	7.00	98.00
	A	20	38.17	29.47	6.59	3.00	109.67

TABLE VII

Time to behavior change

Viewer 1

Group	#	Mean	S.D.	S.E.	Minimum	Maximum
B	20	246.18	401.14	89.70	45.55	1865.50
A	20	316.85	335.67	75.06	37.00	1365.50

Viewer 2

Group	#	Mean	S.D.	S.E.	Minimum	Maximum
B	20	208.50	232.66	52.02	37.97	935.75
A	20	396.47	463.86	103.72	47.90	1561.50

Viewer 3

Group	#	Mean	S.D.	S.E.	Minimum	Maximum
B	20	71.63	79.35	17.74	17.25	250.31
A	20	130.92	159.28	35.62	18.08	547.00

(continued)

(continued)

TABLE VII

Time to behavior change

Group	#	Average Mean	S.D.	S.E.	Minimum	Maximum
B	20	175.44	225.78	50.49	33.91	1016.82
A	20	281.41	300.51	67.20	44.60	1093.67

TABLE VIII

Percentage of time spent in each behavior category (code) as rated by the 3 viewers

Viewer	Group	#	Mean	S.D.	S.E.	Minimum	Maximum
1	B	quiet	20	34.44	30.32	6.78	0.00	90.00
		* annyd	20	26.63	22.69	5.07	0.00	91.00
		upset	20	20.07	17.60	3.93	0.00	61.90
		zoo	20	18.87	28.15	6.29	0.00	95.50
	A	quiet	20	52.86	34.98	7.82	0.00	99.80
		annyd	20	15.54	11.01	2.46	0.20	32.90
		upset	20	19.34	21.86	4.89	0.00	77.20
		zoo	20	12.28	22.65	5.07	0.00	88.00
2	B	quiet	20	32.34	29.77	6.66	0.50	90.40
		annyd	20	35.58	26.49	5.92	0.70	88.70
		upset	20	13.06	11.43	2.56	0.00	35.70
		zoo	20	17.91	24.61	5.50	0.00	88.40
	A	quiet	20	52.45	36.30	8.12	0.00	99.20

(continued)

(continued)

TABLE VIII

Percentage of time spent in each behavior category (code) as rated by the 3 viewers

		annyd	20	17.16	15.63	3.49	0.80	50.30
		upset	20	13.60	17.41	3.89	0.00	53.20
		zoo	20	16.54	24.68	5.52	0.00	94.10
3	B	quiet	20	40.56	27.72	6.20	0.00	90.70
		annyd	20	30.04	22.36	5.00	0.00	92.70
		upset	20	15.34	10.07	2.25	0.00	33.70
		zoo	20	14.02	22.32	4.99	0.00	87.70
	A	quiet	20	54.98	31.93	7.14	0.50	99.70
		annyd	20	21.11	17.17	3.84	0.30	71.70
		upset	20	10.43	10.77	2.41	0.00	35.00
		zoo	20	13.38	20.95	4.69	0.00	77.70
Ave	B	quiet	20	35.78	28.85	6.45	0.77	90.37
		annyd	20	30.75	21.70	4.85	0.23	90.80

(continued)

* annoyd = annoyed

(continued)

TABLE VIII

Percentage of time spent in each behavior category (code) as rated by the 3 viewers

	upset	20	16.16	10.78	2.41	0.00	36.93
	zoo	20	16.93	22.65	5.06	0.00	87.20
A	quiet	20	53.43	33.33	7.45	0.17	99.57
	annyd	20	17.93	11.66	2.61	0.43	38.20
	upset	20	14.45	15.97	3.57	0.00	48.90
	zoo	20	14.06	22.27	4.98	0.00	86.60

TABLE IX

Sedation in operatory rating by the 3 viewers

Viewer	Group	Satisfactory	Unsatisfactory
1	Butorphanol	12	8
	Meperidine	13	7
2	Butorphanol	8	10
	Meperidine	8	10
3	Butorphanol	12	8
	Meperidine	11	9

TABLE X

Sedation in operatory with nitrous oxide rating by the 3 viewers

Viewer	Group	Satisfactory	Unsatisfactory
1	Butorphanol	13	7
	Meperidine	13	7
2	Butorphanol	8	11
	Meperidine	9	10
3	Butorphanol	11	8
	Meperidine	12	7

TABLE XI

Reaction to injection rating by the 3 viewers

Viewer	Group	Satisfactory	Unsatisfactory
1	Butorphanol	10	9
	Meperidine	14	5
2	Butorphanol	11	8
	Meperidine	14	5
3	Butorphanol	10	10
	Meperidine	12	7

TABLE XII

Global scale ratings as rated by the 3 viewers

Viewer	Group	Poor	Fair	Good	Very Good	Excellent
1	B	7	1	6	3	3
	A	6	1	1	4	8
2	B	9	5	3	0	3
	A	7	3	3	1	6
3	B	5	6	5	3	1
	A	6	3	6	2	3

TABLE XIII

Crying ratings as rated by the 3 viewers

Viewer	Group	Screaming	Continuous	Mild	None
1	Butorphanol	4	5	10	1
	Meperidine	3	1	8	8
2	Butorphanol	6	8	4	2
	Meperidine	5	5	5	5
3	Butorphanol	2	7	11	0
	Meperidine	2	5	9	4

TABLE XIV

Cooperation ratings as rated by the 3 viewers

Viewer	Group	Resistant	Difficult	Minor	None
1	Butorphanol	4	4	10	2
	Meperidine	3	4	5	8
2	Butorphanol	2	9	6	3
	Meperidine	5	4	5	6
3	Butorphanol	1	11	8	0
	Meperidine	2	6	9	3

TABLE XV

Apprehension ratings as rated by the 3 viewers

Viewer	Group	Hysterical	Anxious	Mild	Calm
1	Butorphanol	4	3	10	3
	Meperidine	2	5	4	9
2	Butorphanol	6	6	6	2
	Meperidine	7	3	4	6
3	Butorphanol	3	3	14	0
	Meperidine	2	4	11	3

TABLE XVI

Sleep ratings as rated by the 3 viewers

Viewer	Group	Awake	Drowsy	Intermittent	Asleep
1	Butorphanol	3	8	7	2
	Meperidine	4	2	8	6
2	Butorphanol	9	4	5	2
	Meperidine	8	2	5	5
3	Butorphanol	6	5	9	0
	Meperidine	4	3	11	2

TABLE XVII

Operator's dichotomous scale ratings of the sedation and the Fisher's Exact test analysis of statistical significance

		Meperidine		Butorphanol		
Observations	Scale	#	percent	#	percent	p-value
Pre-treatment Frankl	Satisfactory	14	70	12	60	0.741
	Unsatisfactory	6	30	8	40	
Post-treatment Frankl	Satisfactory	10	50	8	40	0.751
	Unsatisfactory	10	50	12	60	
Sedation in Quiet Room	Satisfactory	15	75	15	75	1.000
	Unsatisfactory	5	25	5	25	
Sedation in Operatory	Satisfactory	10	50	5	25	0.191
	Unsatisfactory	10	50	15	75	
Sedation in Operatory with Nitrous Oxide	Satisfactory	15	75	11	58	0.320
	Unsatisfactory	5	25	8	42	
Reaction to Injection	Satisfactory	11	58	8	42	0.517
	Unsatisfactory	8	42	11	58	

TABLE XVIII

Operator's sedation success and global scale ratings and the results of the Cochran-Mantel-Haenszel tests for ordinal data

		Meperidine		Butorphanol		
Observations	Scale	#	percent	#	percent	p-value
Sedation Success	Unsuccessful	1	5	1	5	0.146
	Poor	4	20	5	25	
	Fair	3	15	6	30	
	Good	4	20	5	25	
	Very Good	0	0	0	0	
	Excellent	8	40	3	15	
Global Rating	Poor	2	10	1	5	0.072
	Fair	3	15	9	45	
	Good	5	25	5	25	
	Very Good	2	10	3	15	
	Excellent	8	40	2	10	

DISCUSSION

Thirty-six patients between the ages of 20 and 62 months participated in this study. The patient groups were equally matched for race and gender (meperidine group was 45 percent female and 55 percent male while the butorphanol group was 35 percent female and 65 percent male). The restorative treatment was similar in both groups. There were slightly more extractions in the butorphanol group.

The physiologic parameters that were examined are as follows: blood pressure, oxygen saturation, heart rate, and respiration rate. There was no statistical difference between any of the physiologic data between the meperidine and butorphanol groups, although the meperidine group had a slightly higher mean oxygen saturation rate during treatment of 99.63 percent compared with the butorphanol group's mean of 99.20 percent. This slightly higher oxygen saturation difference of 0.43 percent for the meperidine group was not clinically significant. Hasty et al. in a 1991 sedation study did not consider a pulse oximeter reading a desaturation unless it was below 96-percent oxygen saturation[27] (in fact, both the meperidine and butorphanol groups exhibited mean baseline and mean treatment pulse oximeter ratings greater than 99 percent, which is well above 96 percent). None of the subjects in either group had any desaturation episodes during treatment. Unreported physiologic data occurred due to patient movement (automatic blood pressure cuff and pulse oximeter) and crying (respiration rate). Unreported data may be unavoidable because of the uncooperative behavior of the patient pool. Overall, no adverse reactions occurred and all vital signs were within normal ranges before,

during, and after treatment.

Many of the meperidine subjects exhibited pruritis seen as itching of the nose (not a planned observation, but a known side effect of meperidine). No actual record of the number of occurances or severity of pruritis was made. Butorphanol subjects showed no signs of pruritis.

The butorphanol group's ACS ratings' tendency to spend more percentage of time in the annoyed rating and less time in the quiet rating offers little clinical difference from the meperidine group. These ratings are next to each other on the 4 point rating scale and the difference between a quiet and annoyed rating is not much when compared to the difference between a quiet and zoo rating (at opposite ends of the rating scale). Perhaps a dichotomous scale, or a 2 point behavior rating scale would be more useful in differentiating between the absolute poor and good behaviors by limiting the viewers to one of two choices.

The three trained pediatric dentist viewers showed no statistically significant difference between the categorical scale (Table XIII, XIV, XV, XVI), the dichotomous scale (Table IX, X, XI XII), and the global rating scale (Table XII) when the butorphanol and meperidine groups. This shows that the two groups grossly did not differ in the various behavior rating scales in the mind of the viewers.

Four subjects in each group were repeat subjects. The statistical analysis tabulated them as if they were independent subjects. Whether or not these subjects are analyzed as independent or repeat subjects makes no difference on the dichotomous, categorical, and global rating scales. On the ACS ratings when the subjects are treated as repeat subjects, the meperidine group appears to have better results. It happens that these

four subjects did much better with meperidine than they did with butorphanol. These were only four subjects out of a group of 20. It was decided to treat these subjects as independent subjects, because these four subjects should not cause a shift in the results.

There was no statistically significant difference between the groups in regards to the sedation success rating, but the operators rated the meperidine group with a better global rating than the butorphanol group.

Overall, butorphanol was not superior to meperidine in regards to physiologic or patient behavior effects, but had similar results to meperidine. Neither medication had any adverse events associated with it.

While both groups were effective with some patients as a sedative medication, both groups were not effective 100 percent of the time. An addition of a promethazine or another cosedative may help the effectiveness of both drugs. If no increase in physiologic effects, an increase in butorphanol dosage may help with potential sedation success.

WEAKNESSES IN STUDY DESIGN OR METHOD USED

One weakness in the study design was the inconsistency of using some subjects in both groups and others in only the experimental group or the control group. There is no way to determine what effect the first sedation may have had on the outcome of the second sedation, in those patients who were treated as subjects in both groups. While, this inconsistency casts a shadow of doubt on the reliability of the results, this problem was minimized by blinding the viewers and the operators to the sedative agents being used at each patient visit.

A second weakness of the study was the use of multiple operators. Multiple

operators probably did not have a significant effect on the outcome of this study, because it was designed to compare medications instead of behavior management techniques.

A third weakness of study is the inclusion of nitrous oxide analgesia in addition to the sedation medication. This should have little effect on telling the effectiveness of the experimental medication versus the control medication, because it was used with both groups; however, it could be difficult to tell the true effectiveness of either medication by itself. Clinically, most sedations in dentistry are carried out with nitrous oxide analgesia in addition to any sedation medication, so that this aspect of study design could prove to be more applicable to the "real world" sedation situation.

Considerable physiologic data that should have been recorded by the pulse oximeter and the automatic blood pressure recorder are missing. These missing recordings were unavoidable, because some patients' behaviors disengaged the terminal connectors of the instruments. The missing recordings prevented the collection of complete data, but had no adverse effect on the patients or their therapies.

SUGGESTIONS FOR FUTURE STUDIES

This was the first study to examine the use of butorphanol as a sedative medication in pediatric dental patients. The dosage was determined by the dosages in previously mentioned studies. The dosage selected was a safe level based on these studies. The encouraging results of this study should justify the opportunity for further study of butorphanol for sedation in pediatric dentistry.

A similar study to this one should be completed in the future involving three different intramuscular dosage levels of butorphanol against the same control dosage of

meperidine (2.0 mg/kg). The study should involve the use of the same operator throughout. There should be a minimum of 30 subjects in each group.

Following this, a similar second follow-up study should be attempted using the superior intramuscular dosage of butorphanol and to compare it with and without a co-sedative. These groups would again be compared with a control sedative of meperidine.

Finally, a similar future study should be made using several oral dosages of butorphanol compared with the superior intramuscular butorphanol dosage.

SUMMARY AND CONCLUSIONS

Treating pediatric dental patients who are four years old and younger can be difficult at times due to patient behavior. Conscious sedation has been employed as a means to control pediatric dental patients for several years. All sedative medications have undesirable side effects. Meperidine has been a favored sedative for conscious sedation in pediatric dental patients. The purpose of this study is to compare the behavioral and physiologic effects of conscious sedation on pediatric dental patients using intramuscular meperidine and an equipotent dosage of intramuscular butorphanol. The hypothesis of the thesis is that when intramuscular butorphanol is compared with intramuscular meperidine in an equipotent dosage for sedation of pediatric dental patients, butorphanol will have equal or better quality of level of sedation while displaying equal or less physiological effects on the patient.

Forty conscious sedations of 36 A.S.A. I pediatric dental patients between the ages of 13 and 60 months were accomplished using either 2.0 mg/kg of intramuscular meperidine or 0.03 mg/kg of intramuscular butorphanol. Each sedation was videotaped, and three viewers studied the videotapes rating them with a computer program (ACS) involving a four-code behavior rating scale. The three viewers rated patient behavior for each sedation also with a form with global rating, categorical, and dichotomous scales. Physiologic signs of oxygen saturation, blood pressure, heart rate, and respiration rate were monitored at baseline and every 5 minutes during treatment. The operator also rated the sedation patient behavior with a form that had pre-treatment Frankl, post-treatment

Frankl, global rating categorical, dichotomous, and sedation success rating scales. The two groups' treatment data, physiologic data, ACS data, the three viewer's behavior rating form, and the operator's behavior rating form were analyzed for any statistically significant differences between the groups.

The statistical analysis of the treatment data revealed a statistically significant dental treatment trend in the butorphanol group toward extractions ($p = 0.054$). The meperidine group had a mean oxygen saturation of 99.63 percent during treatment, and this was statistically significant ($p = 0.0806$) when compared with the butorphanol group's mean oxygen saturation of 99.20 percent. This was well above the safe level of desaturation of 96-percent oxygen saturation. The difference between the meperidine group's and the butorphanol group's mean oxygen saturation was clinically insignificant. The butorphanol group spent significantly more time in the annoyed ACS behavior rating code ($p = 0.0886$) and showed a trend toward less time spent in the quiet ACS behavior rating code. This trend in the butorphanol group toward more time in the annoyed ACS behavior rating code and less time spent in the quiet ACS behavior rating code is not clinically significant, due to the subjectivity of a four-point rating scale. There were no statistically significant differences in the three viewers' ratings of global rating, categorical, and dichotomous scales. The operators' ratings showed the meperidine group had a statistically significant better global rating than the butorphanol group ($p = 0.072$). This finding shows that the operators rated the meperidine group as a better sedation agent in a global sense.

The overall success of sedation with butorphanol rated with the ACS rating scale appears to be equal to meperidine in the lack of physiologic side effects and patient

behavior effects. There was minimal physiological impact on the physiologic parameters measured with both medications. No adverse effects occurred with either medication. Intramuscular butorphanol at the dosage of 0.03 mg/kg may be offered as a safe alternative sedative agent to other narcotic sedative agents with more side effects.

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APPENDIX

APPENDIX 1

Frankl behavior rating scale	Wright modification
Refusal of treatment; crying forcefully, fearful, extreme negativism	Definitely negative
Reluctant, uncooperative, limited negativism, sullen, withdrawn	Negative
Accepts treatment but may be cautious or reserved, follows directions	Positive
Good rapport, interested in dental procedures, laughs and enjoys	Definitely positive

APPENDIX 2

Pre-Sedation Instructions

Dear Parent:

In our recent discussion about your child's up-coming dental treatment, we have agreed that it will be necessary to premedicate your child. This premedication will help us to provide the best possible dental treatment in a well-controlled setting. In order to accomplish this safely with the best chance for success, there are certain procedures we ask that you follow before and after the appointment. These are as follows:

1. A child is much influenced by his/her parents' behavior. If you are anxious, upset, and worried about going to the dentist, so will be your child. Please relax.

2. Your child should have a good night's rest before each appointment.

3. Your child should have nothing to eat for at least 6 hours before the appointment. Small amounts of clear liquids are permissible up to 4 hours before the appointment.

4. As legal guardian you must accompany your child.

5. It is very important that your child be in good health for this appointment. Please advise us of the presence of a cold, cough, runny nose, or fever when your appointment is confirmed. Sedation will not be administered when a child is ill.

6. Your child will not be put to sleep, only "relaxed". At times he/she may fall asleep, but can be aroused.

7. Because of the tendency towards drowsiness and clumsiness for several hours, your child should remain indoors and be closely watched for several hours after the appointment.

8. It is normal for the child to sleep after the appointment.

9. In case you have any questions once you are home, call Riley Dental Clinic.

APPENDIX 3

Automated Coding System

Code	Behavior Criteria
Q = quiet	Patient quiet and/or asleep with only extraneous, inconsequential movements.
A = annoyed	Patient cooperative allowing treatment to proceed easily, but with one to two undesirable behaviors present.
U = upset	Patient noticeably disturbed, with two to three undesirable behaviors present, making treatment difficult, but possible.
Z = zoo	Patient extremely defiant with presence of foot movement, torso movement, head movement, and crying to the extent that treatment was difficult or impossible.

APPENDIX 4

Categorical Rating Scale

Crying

1= Screaming

2= Continuous Crying

3= Mild, Intermittent Crying

4= No Crying

Cooperation

1= Violently Resists/Disrupts Treatment

2= Movements which make treatment difficult

3= Minor Movement/Intermittent

4= No Movement

Apprehension

1= Hysterical/Disobeys all instructions

2= Extremely anxious/Disobeys some/Delays treatment

3= Mildly anxious/Complies with support

4= Calm/Relaxed/Follows instructions

(continued)

(continued)

APPENDIX 4

Sleep

1= Fully awake

2= Drowsy

3= Asleep/Intermittent

4= Sound asleep

APPENDIX 5

Dichotomous Scale

A Sedation behavior in operatory	Satisfactory	Unsatisfactory
B Airway maneuver in operatory	Clear	Obstructed
C Sedation behavior in operatory	Satisfactory	Unsatisfactory
D Airway maneuver with nitrous oxide	Clear	Obstructed
E Reaction to injection	Satisfactory	Unsatisfactory

APPENDIX 6

Sedation Success

- Unsuccessful
- Poor
- Fair
- Good
- Very Good
- Excellent

Global Rating

- Poor
- Fair
- Good
- Very Good
- Excellent

CONSCIOUS SEDATION OF THE PEDIATRIC DENTAL PATIENT: A COMPARISON OF MEPERIDINE VERSUS BUTORPHANOL

by

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Treating pediatric dental patients four years old and younger can be difficult at times due to patient behavior. Conscious sedation has been employed as a means to control pediatric dental patients for several years. Butorphanol tartrate has been used safely for pain control in pediatric patients for several years, but has never been used for sedating pediatric dental patients. The purpose of this study is to compare the behavioral and physiologic effects of conscious sedation on pediatric dental patients using intramuscular meperidine and an equipotent dosage of intramuscular butorphanol. Forty conscious sedations of ASA I pediatric dental patients between the ages of 13 and 60 months were accomplished using either 2.0 mg/kg of intramuscular meperidine or 0.03 mg/kg of intramuscular butorphanol. Each sedation was videotaped and three viewers viewed the videotapes rating them with a computer program (ACS) involving a four-code

behavior rating scale. The three viewers rated patient behavior for each sedation also with a form with global rating, categorical, and dichotomous scales. Physiologic signs of oxygen saturation, blood pressure, heart rate, and respiration rate were monitored at baseline and every 5 minutes during treatment. The operator also rated the sedation patient behavior with a form that had pre-treatment Frankl, post-treatment Frankl, global rating categorical, dichotomous, and sedation success rating scales. The two groups demographic data, physiologic data, ACS data, the three viewer's behavior rating form, and the operator's behavior rating form were analyzed for any statistically significant differences between the groups. The statistical analysis of the demographic data revealed a statistically significant trend in the butorphanol group toward extractions. The meperidine group had a statistically significant higher mean oxygen saturation during treatment (99.63 percent) than the butorphanol group (99.20 percent). The butorphanol group spent significantly more time in the annoyed ACS behavior rating code and showed a trend toward less time spent in the quiet ACS behavior rating code. There were no statistically significant differences in the three viewers ratings of global rating, categorical, and dichotomous scales. The operators' ratings showed the meperidine group had a statistically significant better global rating than the butorphanol group. Overall butorphanol appears to be equal clinically to meperidine in physiologic effects and patient behavior effects. No adverse effects occurred with either medication. Butorphanol may be offered as an alternative sedative agent to other narcotic sedative agents with more side effects.

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